

REMARKS/ARGUMENTS

Reconsideration of this Application and entry of this Amendment after Final are respectfully requested. The proposed amendment places the claims in better form for appeal. Additionally, this amendment addresses items brought up by the examiner in the final office action. In view of the amendments and following remarks, favorable consideration and allowance of the application is respectfully requested.

35 U.S.C. §103 Rejections

Obviousness is a question of law, based on the factual inquiries of 1) determining the scope and content of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; and 3) resolving the level of ordinary skill in the pertinent art. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In *re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). See MPEP 2143.03. The Applicant respectfully asserts that the cited references fail to teach or suggest all the claim limitations.

- A. Claims 17-25, 28-38, 40, 41, 43-45 and 47 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Fearnot (US Patent 5,380,299) in view of Mao et al., (US Patent Publication 2003/0022216).

The Applicants submit that the Fearnot patent in view of the Mao publication, fails to disclose, teach, or suggest all of the claim limitations of independent claims 17, 25 and 35. Specifically, Fearnot in view of Mao does not disclose teach or suggest:

1) a drug-polymer coated stent that includes a stent framework, a laminated drug-polymer coating disposed on the stent framework, the laminated drug-polymer coating including a plurality of thin drug-polymer layers, wherein the thin drug-polymer layers include a first therapeutic agent and a cured first polymer, and at least one thin barrier layer positioned between one or more thin drug-polymer layers, wherein the at least one thin barrier layer includes a cured second polymer, wherein the cured second polymer excludes drug interaction between adjacent thin drug-polymer layers, as recited in independent claim 17;

2) a system for treating a vascular condition, that includes a catheter and a coated stent coupled to the catheter, the coated stent including a stent framework and a laminated drug-polymer coating disposed on the stent framework, the laminated drug-polymer coating including a plurality of thin drug-polymer layers and at least one thin barrier layer positioned between one or more thin drug-polymer layers, wherein the thin drug-polymer layers include a first therapeutic agent and a cured first polymer and wherein the thin barrier layer includes a cured second polymer, wherein the cured second polymer excludes drug interaction between adjacent thin drug-polymer layers, as recited in independent claim 25; and

3) a method of treating a vascular condition that includes the step of inserting a drug-polymer coated stent within a vessel of a body, the drug-polymer coated stent including a laminated drug-polymer coating having a plurality of thin drug-polymer layers and at least one thin barrier layer positioned between one or more thin drug-polymer layers, wherein the thin drug-polymer layers include a first therapeutic agent and a cured first polymer and wherein the thin barrier layer includes a cured second polymer, wherein the cured second polymer excludes drug interaction between adjacent thin drug-polymer layers, wherein the first polymer is cured with one of thermal activation, electrical activation, or ionizing irradiation as recited in independent claim 35.

The Examiner continues to rely on the Fearnot patent to teach or otherwise suggest “at least one thin barrier layer positioned between one or more thin drug-polymer layers” as recited in claims 17, 25 and 35. The Examiner cites to column 2 lines 10-25 (reproduced below) and figure 5 of the Fearnot patent to teach these limitations.

10 The method of treating a medical device with a
 thrombolytic agent comprises providing a base material
 for the medical device along with the thrombolytic
 agent. The base material is treated with the thrombo-
15 lytic agent to advantageously dissolve the thrombus on
 the surface of the medical device. The base material is
 advantageously dipped into a solution of the thrombo-
 lytic agent and then removed to allow the thrombolytic
20 agent to dry thereon. The steps of dipping and drying
 the base material and the thrombolytic agent is repeated
 to form a desired concentration or quantity of thrombo-
 lytic agent on the base material. The method further
 includes providing a polymer or a biologically derived
25 material and mixing the thrombolytic agent with the
 polymer or biologically derived material and applying
 the mixture to the base material.

However, column 2, lines 10-25, merely teaches a method of coating a medical device surface by dipping the device into a solution containing a thrombolytic agent, allowing the solution to dry and repeating the dipping and drying, if necessary, to obtain the desired concentration or quantity of the thrombolytic agent on the device surface. Figure 5 of the Fearnot patent merely teaches a stent framework having a multi-layer coating, the multi-layer coating having three layers of an antithrombogenic agent and three layers of a thrombolytic agent applied over the antithrombogenic layers (see Fearnot col. 3 lines 47-50). Nowhere within the cited portions or the entirety of the Fearnot patent, does the Fearnot patent teach or fairly suggest that any of the layers of the multi-layer coating is a barrier layer having a cured second polymer, wherein the cured second polymer excludes drug interaction between adjacent thin drug-polymer layers as claimed and described by the Applicants. The mere fact that the Fearnot patent teaches a multi-layer coating does not necessarily teach that any of the layers are barrier layers. Therefore, the Fearnot patent does not teach at least one thin barrier layer positioned between one or more thin drug-polymer layers, as recited in claims 17, 25 and 35. The Mao publication does not cure this defect. For at least this reason, claims 17, 25 and 35, and the claims depending therefrom, are patentable over the Fearnot patent in view of the Mao publication.

Claims 18-21, 28-31, 37, 40, 41, 43-45 and 47 each depend from one of independent claims 17, 25 and 35 and include all of the limitations of their respective independent claim. For at least this reason, dependent claims 18-21, 28-31, 37, 40, 41, 43-45 and 47 are patentable over the Fearnot patent in view of the Mao publication. Claims 22-24, 34, 36 and 38 were cancelled in the amendment to the claims filed June 12, 2006. The Applicants respectfully request the withdrawal of the rejection of claims 17-25, 28-38, 40, 41, 43-45 and 47 as being unpatentable over the Fearnot patent in view of the Mao publication

B. Claims 26 and 27 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Fearnot in view of Mao and in further view of Guruwaiya (US Patent 6,251,136).

Claims 26 and 27 depend from independent claim 25 and include all of the elements and limitations of independent claim 25 and, thus, are allowable for at least the same reasons as those stated above for claim 25. Furthermore, where an independent claim is non-obvious, any claim depending therefrom is also non-obvious. *See*, MPEP 2143. Applicants, therefore, request the

withdrawal of the rejection of dependent claims 26 and 27 under § 103(a) as being unpatentable over Fearnot in view of Mao and in further view of Guruwaiya.

C. Claims 42 and 46 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Fearnot in view of Mao and in further view of Helmus et al., (US Patent 5,447,724).

Claims 42 and 46 depend from independent claims 17 and 25, respectively, and include all of the elements and limitations of independent claims 17 or 25 and, thus, are allowable for at least the same reasons as those stated above for claims 17 and 25. Furthermore, where an independent claim is non-obvious, any claim depending therefrom is also non-obvious. *See*, MPEP 2143. Applicants, therefore, request the withdrawal of the rejection of dependent claims 42 and 46 under § 103(a) as being unpatentable over Fearnot in view of Mao and in further view of Helmus.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-5021.

Respectfully submitted,

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